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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,249	02/12/2004	Gregory O. Ness	P10959.00	5389

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EXAMINER	
SMITH, PHILIP ROBERT	
ART UNIT	**PAPER NUMBER**
3739	

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/777,249	NESS, GREGORY O.	
	Examiner	Art Unit	
	Philip R. Smith	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *11-30* is/are withdrawn from consideration.

5)☒ Claim(s) *31-50* is/are allowed.

6)☒ Claim(s) *1-3 and 5-10* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/12/04, 3/30/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restrictions

[01] As per the response to restriction requirement of 2/21/2006, claims 11-30 are withdrawn without traverse from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group.

Specification

[02] The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

[03] Claims 1 & 3 are objected to because of the following informalities. Appropriate correction is required.

[04] In claim 1, "a" is used in several places where "an" is appropriate. In the second indented paragraph, the phrase "extending laterally of the access instrument body axis" is problematic. As noted below, it was interpreted "extending laterally from..."

[05] In claim 3, "the incision" should read "an incision" or be struck from the claim.

Claim Rejections - 35 USC § 103

[06] The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art

to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[07] Claims 1-3, 5 & 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donofrio (6,277,065) in view of Adams (2003/0018236).

[08] With regard to claim 1: Donofrio discloses an access instrument for accessing an anatomic space between anatomic surfaces in a patient's body comprising:

[08a] an elongated access instrument body formed of an elastomer ("catheter 40... made of polyethylene," 4/30) extending between a access instrument body proximal end and a access instrument body distal end ("cap 39," 4/16), the elongated access instrument body having [an] access instrument body axis, [an] access instrument body width in a width direction, and [an] access instrument body thickness in a thickness direction substantially orthogonal to the width direction,

[08b] the elongated access instrument body enclosing an inflation lumen ("means for inflating and deflating the balloon 30," 4/23) extending from the access instrument body proximal end through the access instrument body to an inflation lumen distal end opening and a working lumen ("working channel 24," 3/7) extending from the access instrument body proximal end through the access instrument body to the access instrument body distal end; and

[08c] a distal header ("distal end section 12") coupled to the access instrument body distal end comprising a header body (composing "cap 39," 4/21, "major peripheral part 14" and "minor peripheral part 15," 3/15) supporting a

header plate extending laterally [from] the access instrument body axis in the width direction to [an] atraumatic plate rim ("minor peripheral part 15," 3/26);

[08d] the header plate having a first plate side ("window 18," 3/29) bounded by the atraumatic plate rim ("15," as noted above),

[08e] the header body enclosing a header lumen ("working channel 24," as noted above) extending between the working lumen at the access instrument body distal end and a working lumen exit port through the first plate side ("window 18," as noted above), and

[08f] an inflatable balloon ("balloon 30") mounted to the plate and adapted to be inflated by introduction of inflation media ("fluid," 4/26) through the inflation lumen distal end opening into an inflation space between the balloon and at least a portion of the first plate side,

[08g] whereby the inflation of the inflatable balloon expands an anatomic space between anatomic surfaces ("wall 27 of a passage surrounding the endoscope 10," 3/66) and disposes the working lumen exit port spaced from an anatomic surface.

[09] Donofrio does not disclose that the access instrument body width exceeds the access instrument body thickness enabling bending of the access instrument body in the thickness direction and resisting bending of the access instrument body in the width direction.

[10] Adams discloses the following in [0023]:

> These non-circular devices have numerous advantages over existing circular devices.... may be more flexible and therefore more easily bend forwards a desired location...

[11] At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the thickness and width of the instrument body disclosed by Donofrio such that the width exceeds the thickness. A skilled artisan would be motivated to do so in order that the device "more easily bends forwards [sic] a desired location."

[12] With regard to claim 2: The balloon ("30," as noted above) supported by the header plate disclosed by Donofrio substantially surrounds the working lumen exit port ("18," as noted above).

[13] With regard to claim 3: Donofrio discloses that the header body and header plate (which compose the distal header, or "distal end section 12," as noted above) extend distally from the access instrument body. The distal segment of the atraumatic plate rim ("15," as noted above) may be used to separate anatomic surfaces along a pathway to the anatomic space as the access instrument body is advanced into [an] incision and along the pathway.

[14] With regard to claim 5: Donofrio discloses that the access instrument body incorporates a light pipe having a light pipe proximal end adapted to be coupled to a light source external to the patient's body and extending to a light pipe distal end, and the distal header comprises a light emitter coupled to the light pipe distal

end that emits light generated by the light source and conducted through the light pipe in a region adjoining the working lumen exit port ("illumination device 20," 2/66).

[15] With regard to claim 7: The light emitter disclosed by Donofrio comprises a light ring disposed in the first plate side in proximity to the balloon and the working lumen exit port (see Figure 1).

[16] With regard to claims 8 & 9: The light emitter disclosed by Donofrio has a surface from which the light is emitted, which anticipates a faceted outer surface.

[17] With regard to claim 10: The first plate side ("window 18," as noted above) disclosed by Donofrio is substantially planar (see Figure 2) and surrounded by the atraumatic plate rim ("minor peripheral part 15," as noted above). The first plate side disclosed by Donofrio is substantially in parallel to the access instrument body axis (see Figure 2), whereby the first plate side is disposable in proximity to a first anatomic surface when the inflatable balloon is deflated, and is disposed away from the first anatomic surface when the inflatable balloon is inflated (see Figure 2).

Additional Claim Rejections - 35 USC § 103

[18] Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Donofrio in view of Adams, and in further view of Barthel (2004/0015052).

[19] Donofrio in view of Adams discloses a balloon made of polyethylene (4/30), but does not disclose that the balloon is substantially transparent to emitted light.

[20] Barthel discloses a "balloon catheter 10" comprising "a dilation balloon portion 11, typically made of clear, non-distensible polymer material such as transparent polyethylene" ([0024]).

[21] At the time of the invention, it would have been obvious to a person of ordinary skill in the art that the "balloon 30" be made of polyethylene which is transparent. A skilled artisan would be motivated to do so in order to see through the balloon. It is clear from the disclosure of Barthel that balloon are "typically" constructed in this manner.

Allowable Subject Matter

[22] Claims 31-50 are allowed. The following is an examiner's statement of reasons for allowance.

[23] The apparatus disclosed by Donofrio may be capable of use in accordance with the method recited in claim 31, but is not disclosed for use in a method which includes: surgically creating an incision into the anatomic space between the first and second anatomic surfaces; inserting the distal header through the incision with the first plate side disposed facing the first anatomic surface; advancing the distal header through the anatomic space between the first and second anatomic surfaces with the first plate side disposed facing the first anatomic surface; inflating the balloon to expand the anatomic space between the first and second anatomic surfaces; introducing one of a visualization instrument through the working lumen to visualize the anatomic space and the first anatomic surface to select a site of the first anatomic surface, a medical instrument through the

working lumen for performing a medical procedure, an implantable medical device through the working lumen into the anatomic space, and a therapeutic drug or diagnostic agent through the working lumen into the anatomic space.

[24] Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

[25] Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The Prior Art does not disclose separately filled balloons.

Conclusion

[26] The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Callaghan (Re. 35,531), Fortuna (7,040,322) & Brain (4,509,514) separately disclose a laryngeal mask with an annular balloon at the distal tip. Yozu (2003/0167038) discloses an occlusion catheter with drug delivery capabilities.

[27] Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip R. Smith whose telephone number is (571) 272 6087 and whose email address is philip.smith@uspto.gov. The examiner can normally be reached between 9:00am and 5:00pm.

[28] If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272 4764.

[29] Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prs

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